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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/292,437	04/15/1999	OLAF SCHNEEWIND	510015.213	3556

7590

03/21/2002

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EXAMINER
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NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/21/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/292,437

Applicant(s)

Schneewind et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 22, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14-16, 18-20, 22-24, and 26-97 is/are pending in the application.
- 4a) Of the above, claim(s) 1-7 and 26-97 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 16, 20, and 24 is/are allowed.
- 6) ☒ Claim(s) 9, 15, 19, and 23 is/are rejected.
- 7) ☒ Claim(s) 8, 14, 18, and 22 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's amendment filed January 22, 2001 (Paper Number 20) has been received and entered. Claims 11-13, 17, 21 and 25 have been canceled. Consequently claims 1-10, 14-16, 18-20, 22-24 and 26-97 are pending in the instant application, of which claims 1-7 and 26-97 have been withdrawn from further consideration as being drawn to a non-elected invention in Paper Number 18.

Additionally Applicant's have amended claim 8 to recite nucleic acid sequences encoding SEQ ID NO: 3 and sequences incorporating one or more conservative amino acid substitutions in SEQ ID NO: 3 including any of isoleucine for leucine, and valine for any other of these amino acids, aspartic acid for glutamic acid and vice versa, glutamine for asparagine and vice versa, and serine for threonine and vice versa. However, as set forth in MPEP 823.04 nucleic acids encoding biological molecules with different sequences are independent and distinct inventions. Furthermore, this position was also set forth in the restriction requirement mailed March 14, 2001 (Paper Number 16), and in response Applicant's have elected the nucleotide sequence encoding the protein of SEQ ID NO: 3 (response filed May 21, 2001). Consequently, the limitations found in claim 8 reciting particular substitutions within SEQ ID NO: 3 are withdrawn from further consideration as being drawn to a non-elected invention.

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***Claim Rejections - 35 USC § 101***

1. The rejection of claims 8-13 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicant's amendment.

***Claim Rejections - 35 USC § 112***

2. The rejection of claims 11-13, 17, 21, and 25 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the cancellation of said claims.
3. The rejection of claims 10-13, 16-17, 20-21, and 24-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendment.
4. The rejection of claims 10-13, 16-17, 20-21, and 24-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendment.

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5. The rejection of claims 11-13, 17, 21, and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of said claims.

6. The rejection of claims 8-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendment.

7. The rejection of claims 11-13 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "greater than about." is withdrawn in view of Applicant's amendment.

***Claim Rejections - 35 USC § 102***

8. The rejection of claims 11-13, 17, 21 and 25 under 35 U.S.C. 102(b) as being anticipated by Kunsch et al is withdrawn in view of the cancellation of said claims.

***Double Patenting***

9. The rejection of claims 9, 15, 19, and 23 under 37 CFR 1.75 as being a substantial duplicate of claims 8, 14, 18 and 22 is maintained. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

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difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant's are asserting that claims 8 and 9 do not cover the "same thing." Applicant's further assert that the literal scope of claim 8 covers isolated nucleic acid molecules encoding a polypeptide comprising SEQ ID NO: 3, and certain variants of such polypeptides comprising well-defined conservative amino acid substitutions, while claim 9 is directed to isolated nucleic acid molecules encoding a polypeptide comprising SEQ ID NO: 3.

Applicant's arguments are not found to be fully persuasive in view of the restriction requirement mailed March 14, 2001 (Paper Number 16). The restriction requirement specifically set forth that the instant application was restricted to a nucleotide sequence encoding one single protein including substitutions. (See page 3). Consequently, Applicant's claimed differentiation of variants (substitutions) encompassed within claim 8 has been withdrawn from consideration, and the resulting claimed nucleic acid sequence is thereby the "same thing" as claimed in claim 9.

For reasons of record in Paper Number 19, as well as the recited reason give above, this rejection is maintained.

Claims 8-9, 14-15, 18-19 and 22 are objected to as encompassing non-elected inventions. Claims 10, 16, 20 and 24 are allowed.

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10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

March 20, 2002